#### REMARKS

Claims 16, 29 and 37 were amended herein. Claims 14, 16-22 and 24-55 are currently pending and under consideration.

# Claim Objection

Claim 29 was objected to for recitation of the term "film flake". Applicants have amended the claim by deleting the term "film" to overcome this objection.

# Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 17 and 40 were rejected as allegedly being indefinite for recitation of the phrase "substantially clear". The rejection alleges that the term is not adequately defined. Applicants respectfully submit that the term is indeed adequately defined in the specification. Paragraph [0010] in the specification explicitly states that "[T]he term "substantially clear" when used in to describe the present invention shall mean translucent or transparent." Therefore, as used in claims 17 and 40, the term "substantially clear" refers to a gel that is translucent or transparent. Applicants submit that the rejection is improper, and request reconsideration and withdrawal of the rejection.

### Rejections Under 35 U.S.C. § 103(a)

1. Claims 16-19, 24, 28-32, 34-37, 40-42, 47, 52 and 55 were rejected as allegedly being obvious over Hauschild et al. (U.S. Patent No. 4,440,877). It is the Examiner's view that Hauschild would lead one of skill in the art to arrive at claims 16-19, 24, 28-32, 34-37, 40-42, 47, 52 and 55, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

While not necessarily in agreement with the Examiner's grounds for rejection,
Applicants have amended claims 16 and 37 herein to advance prosecution. Specifically,
Applicants have amended claims 16 and 37 to reflect that the hydroxyalkyl cellulose of the
flakes is a hydroxyalkyl methyl cellulose. Support for this amendment can be found

throughout the as-filed application, and for example, in paragraph [0012]. No new matter is believed to be added by way of these amendments.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graliam* v. *John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103 ...

- [T]he four factual inquires enunciated therein as a background for determining obviousness are as follows:
- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141)

When applying 35 U.S.C. § 103(a), the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141 II). None of these criteria have been met here.

When Hauschild is read as a whole, the skilled artisan would understand Hauschild to teach very specific agglomerate speckles containing a functional material and binders, wherein the binders are a mixture of ethyl cellulose and a water soluble binder. For example, Example 6 of Hauschild explicitly demonstrates that compositions which lack ethyl cellulose rapidly degrade and are unsuitable for the intended use. The skilled artisan would understand Hauschild to require ethyl cellulose, and, significantly, to be inoperable in the absence of ethyl cellulose.

In contrast, the present invention is directed to oral compositions containing flakes which comprise a water soluble hydroxyalkyl methyl cellulose polymer. When viewing the present invention as a whole, and when reading Hauschild as a whole, the skilled artisan would actually be led away from Applicants' presently-claimed invention, for the

presently-claimed invention requires methyl cellulose. In this way, Hauschild can be interpreted as teaching away from the claimed invention.

Because Hauschild teaches the requirement of ethyl cellulose, rather than methyl cellulose, the skilled artisan would have no reasonable expectation of success in arriving at the presently-claimed invention. Applicants therefore submit that Hauschild does not render obvious the present claims, as amended, and respectfully request reconsideration and withdrawal of the rejection.

2. Claims 14, 15, 20-22, 25-27, 38, 39 and 43-54 were rejected as allegedly being obvious over Hauschild in view of Rajaiah (U.S. Patent Application Publication No. 2002/0187108). It is the Examiner's view that Hauschild in view of Hill would render obvious the claims, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

The rejection is based on Hauschild, for the same reasoning as set forth for the rejection based on Hauschild alone. Applicants' arguments over Hauschild therefore apply with equal force herein. The Rajaiah reference does not remedy the deficiencies of Hauschild. That is, Rajaiah, when read as a whole, does not teach that a composition as taught by Hauschild, could be successfully prepared without using ethyl cellulose. Rajaiah does not provide any teaching or suggestion that methyl cellulose could be successfully used.

Accordingly, Applicants' submit that Hauschild and Rajaiah, when viewed together, do not provide the requisite teaching, suggestion, or motivation to arrive at Applicants' presently-claimed invention. Therefore, the combination of references does not provide the skilled artisan with any reasonable expectation of success in arriving at Applicants' claimed invention. Applicants respectfully submit that the references therefore do not render obvious claims 14, 15, 20-22, 25-27, 38, 39 and 43-54, and request reconsideration and withdrawal of the rejection.

### **SUMMARY**

Applicants believe that claims 14, 16-22 and 24-55 are in condition for allowance and favorable consideration is solicited. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

BOYD et al.

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